vaccine development such as Virus Like Particles (VLPs) and DNA vaccines.

Efforts to improve the existing vaccine strategy at the National Institute of Immunology, an Institute under the DBT, have resulted in the development of a tissue.culture based vaccine for JE using an Indian strain in contrast to the existing formalin-inactivated vaccine based on a Japanese Nakayama strain produced in sucking mice brain at Central Research Institute, Kasauli.

The package of technologies have been transferred to M/s. Panacea Biotech Limited, Delhi. The clinical trials for its safety and efficacy would be undertaken once the vaccine is ready for the same.

(c) As per reports received from the State Health Authorities, the number of deaths due to JE during the last two years in the States of Maharashtra, Uttar Pradesh, Bihar and West Bengal have been as under:—

Sl. No.	Name of the State	2002	2003
1.	Bihar	1	2
2.	Maharashtra	16	115
3.	Uttar Pradesh	133	237
4.	West Bengal	105	1

Banned drugs

1675. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that there are many drugs available in the country which have been banned abroad;

(b) if so, the names of such drugs; and

(c) what action is being taken against the companies marketing such medicines in India?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) to (c) Drugs

are not banned in the country automatically because of their withdrawal in another country. Reports of withdrawal of drugs in a country are examined after taking into account the adverse event reported, reasons for withdrawal; its usage and strength permitted; its requirement in the country, details of scientific studies and the overall risk benefit ratio of banning the drug. A drug considered harmful or irrational for use in the country by the regulatory authority is prohibited throughout the country for manufacture and sale through a Gazette Notification. Marketing of a prohibited drug is an offence under the Drugs and Cosmetics Act 1940, and the offenders are liable to be prosecuted.

Licensing rules of medicines

1676. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what action has been taken by the Drug Controller General of India (DCGI) office to tighten the licensing rules for new medicines; and

(b) the details of existing licensing rules for new medicines?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE) SHRIMATI PANABAKA LAKSHMI): (a) and (b) The rules for licensing of new medicines (New Drugs) prescribed under Rule-122A to E of Drugs and Cosmetics Act and Rules thereunder, were amended *vide* Gazette Notification GSR No. 900(E) dt. 12.12.2001, which streamlined the procedures *viz.* application forms and fee requirements etc. Schedule-Y of Drugs and Cosmetics Rules which provides for requirement of pre-clinical, toxicological and human clinical studies etc. for new drugs has also been recently revised.

These rules are also available at departmental website *www. cdsco. nic. in.*

Further, to restrain State Licensing Authorities from granting of New Drug licenses without approval of competent authority, Rules 69,71,75 & 76 of Drugs & Cosmetics rules were amended *vide* Gazette Notification GSR No. 311 (E), dt. 1.05.2002.